



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 6, 2020

Shannon Payne
Manager of Operations
Current Technologies
P.O. Box 21
Crawfordsville, IN 47933

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: HYPE-WIPE
EPA Registration Number: 70590-1
Application Date: July 16,2020
Decision Number: 564737

Dear Ms. Payne:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Norovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



John Hebert, Chief
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

AVOID CONTACT WITH CLOTHING TO AVOID DISCOLORATION

← Tear Here →

HYPE-WIPE® DISINFECTING TOWEL WITH BLEACH

Disinfect hard, non-porous surfaces including plastics, glass, glazed ceramic tile, linoleum, laminated plastic counters, baked enamel, Plexiglas®, glazed porcelain, some grades of stainless steel. For disinfecting stainless steel, follow equipment manufacturers' directions which may require rinsing after Hype-Wipe® application.

Disinfecting Sites / Applications for Hype-Wipe® towels:

	Clinical	Lab Equip. & POC Devices	Other Sites
ICU / OR / ER	• External surfaces of	• Blood glucose meters	Wastewater facilities
Nursing stations	ultrasound transducers,	• Analyzers for Blood Gas,	Restrooms
Patient rooms	probes, dialysis,	Chemistry, Coagulation	Ambulance/EMS backboard
Clinics/outpatient	respiratory equipment	• Molecular, DNA testing &	Nursing home/wheelchairs
Surgery centers	• Countertops	diagnostic equipment	Veterinarian facilities
Blood banks	• IV poles / pumps	• Centrifuges	Correctional centers
Specimen collection	• Gurneys / bed rails	• Phlebotomy trays / carts	Schools / daycare
MD/dental offices	• Blood pressure cuffs	• Benchtops / sinks	Health clubs

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. (1) Remove all gross filth and heavy soil from surfaces to be disinfected. Gloves should be worn. (2) Open pouch, remove towel. Use towel and excess liquid to wipe surface. (3) Allow solution to remain wet on surface for at least two minutes to inactivate a broad range of micro-organisms. Leave wet four minutes to kill C. diff spores. See front panel for specific pathogen kill times. (4) Rinsing: Some equipment / surfaces such as stainless steel may require rinsing; follow those specific manufacturers' directions.

SPECIAL CLEANING PROCEDURE BEFORE DISINFECTING AGAINST C. DIFF SPORES: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

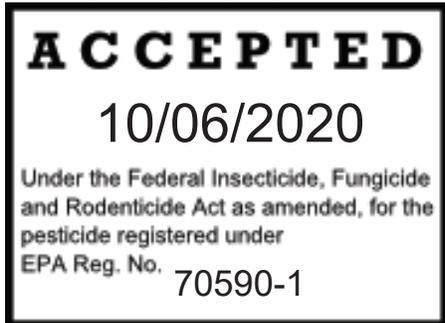
SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON SURFACES / OBJECTS SOILED WITH BLOOD/BODY FLUIDS on pre-cleaned environmental surfaces/objects previously soiled with blood / body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling inanimate surfaces / objects with blood or body fluids, and in which the surfaces / objects soiled with blood or body fluids can be associated with the potential for transmission of HBV and HCV.

INFECTIOUS MATERIALS DISPOSAL: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

PERSONAL PROTECTION: Wear appropriate barrier protection such as gloves, gowns, masks or eye coverings. *STORAGE: Towellets must be stored in a cool, dry area at room temperature (68° - 77°F) away from sunlight and heat. DISPOSAL: Discard used towel and empty pouch in trash.

PRECAUTIONARY STATEMENTS: Physical and Chemical Hazards: Do not use this product with ammonia, acids (such as vinegar), rust removers, toilet bowl cleaners, or heavy metals such as copper and iron. Will corrode aluminum.

CAUTION: Avoid contact with eyes. If in eyes, slowly rinse eye with water for 15-20 minutes. Seek medical guidance.



AVOID CONTACT WITH CLOTHING TO AVOID DISCOLORATION



HYPE-WIPE®

DISINFECTING TOWEL WITH BLEACH

Hospital Cleaner – Disinfectant • Kills C. diff spores in 4 Minutes

Ready-to-use towelettes saturated with 1:10 dilution of stabilized bleach and detergent solution. Contains at least 5500 ppm bleach at expiration with proper storage*. Meets OSHA, NCCLS, CDC blood-borne pathogen standards for disinfection.

Kill Time	Bacteria
One Minute	<ul style="list-style-type: none"> • Enterobacter cloacae NDM-1 • Escherichia coli (ESBL) • Escherichia coli NDM-1 • Klebsiella pneumoniae NDM-1 • Carbapenem-Resistant Klebsiella pneumoniae (CRKP) • Multi-drug Resistant (MDR) Enterococcus faecium • Multi-drug Resistant (MDR) Staphylococcus aureus • Tuberculosis – TB (Mycobacterium bovis – BCG) • Vancomycin-Resistant Staphylococcus aureus (VRSA)
	<ul style="list-style-type: none"> • Pseudomonas aeruginosa • Salmonella enterica • Streptococcus pyogenes
Two Minutes	<ul style="list-style-type: none"> • Methicillin Resistant Staphylococcus aureus (MRSA) • Staphylococcus aureus • Vancomycin Resistant Enterococcus faecium (VRE)
	<ul style="list-style-type: none"> • Clostridium difficile Spores (C. diff spores)
Four Minutes	<ul style="list-style-type: none"> • Hepatitis B (HBV) • Hepatitis C (HCV) • Influenza A H1N1 (swine flu)
	<ul style="list-style-type: none"> • Norovirus • Respiratory Syncytial (RSV) • Rotavirus

<<EMERGING VIRAL PATHOGENS CLAIMS – Hard, non-porous surfaces>>

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

-Enveloped Viruses:

For an emerging viral pathogen That is a/an	...following the directions for use For the following organisms on the label
Enveloped virus	Norovirus

-Large, non-enveloped viruses:

For an emerging viral pathogen That is a/an	...following the directions for use For the following organisms on the label
Large, Non-Enveloped virus	Norovirus

HYPE-WIPE® has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, HYPE-WIPE® can be used against [name of emerging virus] when used in accordance with the directions for use against norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness / outbreak] is caused by [name of emerging virus]. HYPE-WIPE® kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

Active Ingredient: Sodium Hypochlorite 0.94%
 Other ingredients..... 99.06%
 Total..... 100.00%
 Available Chlorine: .9% EPA Reg. No. 70590-1 EPA Est. 70590-IN-1
 Towel: Folded 6" x 12" Net Wt. 12.2 grams (excludes towel)

current technologies, inc.
 P.O. Box 21 • Crawfordsville, IN 47933 U.S.A.
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RE-ORDER # 9103